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Customer No.: 26308

Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Pettersson et al

Attorney Docket No.: 9404.20834

Serial No.: 10/531,598

Examiner: Micah-Paul Young

Filed: November 25, 2005

Group Art Unit: 1618

Title: Gastric Acid Secretion Inhibition Composition

SUBMISSION OF SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. § 1.97 (d) (AFTER NOTICE OF ALLOWANCE)

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

01/05/2010 JADD01 00000041 10531598
01 FC:1464 130.00 OP

01/05/2010 JADD01 00000041 10531598
02 FC:1806 180.00 OP
03 FC:9998 10.00 OP

Dear Sir:

Applicant hereby submits a Supplemental Information Disclosure Statement Pursuant to 37 C.F.R. § 1.97(d). The requisite fee accompanies this submission.

A Notice of Allowance for this application was mailed October 21, 2009.

The Supplemental Information Disclosure Statement lists an Office Action mailed September 29, 2009 in related Application Serial No. 10/475,254 (Examiner Susan Tran, Art Unit 1615) (in shorthand, the "Office Action"). Related Application Serial No. 10/475,254 will also in shorthand be called the "Related Application." The Office Action rejects claims 32, 38, 48 to 60, and 62 to 65 pending in the Related Application under 35 U.S.C. § 103(2) as being unpatentable over Goldman et al (U.S. 5,204,118) in view of Depui et al US 6,132,771. Both Goldman et al and Depui et al are of record as having been considered in the instant application. However, no item of information contained in the information disclosure statement pertaining to the combination of Goldman et al and Depui et al in the Related Application was cited in a communication from a foreign patent office in a counterpart application and, to the knowledge of the undersigned attorney of record, after making reasonable inquiry, no item of information contained in the information disclosure statement pertaining to the combination of Goldman et al and Depui et al in the Related Application was known to any individual designated in § 1.56(c) more than three months prior to

the filing of the information disclosure statement. The Office Action was not received by the Applicant by mail until October 1, 2009, and this Submission is being filed on the first business day of the Patent Office following New Years Day January 1, 2010.

The Examiner will recall that, in the instant application, a Declaration of Nimish Vakil, M.D., FACP, FACG was submitted. The contents of Dr. Vakil's Declaration were discussed during a personal interview with the Examiner on 27 May 2009, which Dr. Vakil attended. Following consideration of the contents of Dr. Vakil's Declaration, the prior art rejections of the claims in the instant application (now allowed) were withdrawn.

In the Related Application, Dr. Vakil has also prepared and signed a Declaration, entitled the Second Supplementing Declaration of Nimish Vakil, M.D., FACP, FACG, a copy of which accompanies this Submission. Dr. Vakil's Second Supplementing Declaration is being submitted to Examiner Tran in the Related Application. A personal interview with Examiner Tran in the Related Application is scheduled for January 7, 2010, which Dr. Vakil will also attend, to discuss with Examiner Tran the contents of Dr. Vakil's Second Supplementing Declaration.

In his Declaration in the Related Application, Dr. Vakil explains, from a historical perspective, the state of thought by persons of ordinary skill in the art pertaining to GERD to demonstrates why, at the time of the invention, he and his colleagues and other persons of ordinary skill in the art pertaining to GERD would not have considered combining an H2RA and a PPI for co-administration in the treatment of GERD (¶¶ 9 to 24). This is the same state of thought and prejudice described by Dr. Vakil in his Declaration previously submitted in the instant application (see, e.g., ¶ 41 of Dr. Vakil's Declaration previously submitted in the instant application: "At that time, my colleagues and I believed that, in the absence of a stimulated parietal cell, the PPI would remain inactive, unable to exert its effect and thereby served no purpose. Since H2RA's blocked the H2 Receptor, they blocked the stimulation of the parietal cell in the first instance, so the co-administration of a PPI with the H2RA simultaneously or concomitantly made no scientific or pharmacological sense to me or my colleagues at that time. However, for the same reason, it did make scientific and pharmacological sense why it was never appropriate to co-administer a H2RA and PPI simultaneously or concomitantly.").

In his Declaration in the Related Application, Dr. Vakil explains, from this historical perspective, why a person of ordinary skill in the art pertaining to GERD at the time of the Invention would not have been motivated by Goldman to co-administer H2RA and PPI in the treatment of GERD (¶¶ 25 to 41). This is the same lack of motivation described by Dr. Vakil in his Declaration previously submitted in the instant application (see, e.g., ¶ 42 of Dr. Vakil's Declaration previously submitted in the instant application: "At a time prior to the invention, my colleagues and I understood that the co-administration of H2RA and PPI would prevent the PPI from exerting its antisecretory effect, and that we would be doing the patient a disservice by not allowing the PPI to act. The concept was that one drug (the H2RA) bars the other (the PPI) from working, so if you gave the two together, they interfered with each other. Furthermore, PPI's were (and still are) expensive. Therefore, not only did we think that there was a potential therapeutic disadvantage when you combine these drugs, to co-administer would put the patient at an economic disadvantage. At a time prior to the invention, there was no scientific, clinical, or pharmacologic rational for the co-administration of H2RA's and PPI's and, instead, all scientific and pharmacologic beliefs argued against it.").

In his Declaration in the Related Application, Dr. Vakil describes the "breakthough" nature of the Invention ((¶¶ 42 to 46). This is the same evidence of objective indications of nonobviousness described by Dr. Vakil in his Declaration previously submitted in the instant application (see, e.g., ¶ 47 of Dr. Vakil's Declaration previously submitted in the instant application: "The data are surprising and unexpected in that the co-administration of PPI and H2RA works at all, let alone better than the individual doses. We do not fully understand why this is the case at this time. This is why the Invention challenges my colleagues and me to look again at how these drugs work on acid secretion, and look at it from different perspectives than we have in the past. The Invention has changed our views, and the empirical data test or challenge a well held view. The data from our study show that acid inhibition by the Invention is prompt, additive, and prolonged, if desired.")

In his Declaration in the Related Application, Dr. Vakil describes additional evidence of nonobjective indications of nonobviousness that was not available at the time he prepared his Declaration for the instant application (see ¶ 43: "The Invention (identified by the drug

designation OX17) has been clinically tested in a Phase II trial conducted by the assignee of the current application, Orexo AB. In a recent article "The Next Blockbuster Drugs" (Newsweek, July 22, 2009) (Attachment 22), OX17 is identified under the category of Heartburn Drugs as being a Potential Blockbuster (the only one so identified in this category):

"The Potential Blockbusters:

"There appear to be few significant near-term challengers on the horizon to the Nexium; the drug does not start coining off patent until 2015. But one company with a candidate that could be a contender is Orexo AB, with its OX17 proton pump inhibitor. It is being developed for the treatment of gastro esophageal reflux disease, the most serious form of acid reflux. It combines two substances in an effort to provide both long-lasting and fast-acting heartburn relief."

"In a Phase II trial last year, OX17 quickly proved effective in working fast and continuing to work to reduce stomach acid. Earlier this year, Orexo signed an exclusive development deal with a yet-to-be-named partner. The company expects to announce a licensing deal for its OX17 program this year, as well.").

For the reasons set forth in Dr. Vakil's Declaration previously filed in the instant application, as restated in his Second Supplementing Declaration filed in the Related Application, neither Goldman et al (U.S. 5,204,118) nor Depui et al US 6,132,771 are believed to be pertinent to the invention defined in the allowed claims in the instant application.

Respectfully Submitted,

By_____
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